

**ARGUMENT SUPPORTING PRE-APPEAL BRIEF REQUEST FOR REVIEW
IN U.S. PATENT APPLICATION NO. 10/815,282**

All pending claims of U.S. Patent Application No. 10/815,282 have been twice rejected under 35 U.S.C. 103(a) over U.S. Patent No. 6,976,950 to Connors et al. ("Connors") – most recently on December 19, 2007. As demonstrated below, clear factual and legal deficiencies exist in the claim rejections, such that withdrawal of the claim rejections under 35 U.S.C. 103(a) is warranted.

It is elementary that, to support a rejection under 35 U.S.C. 103, **the prior art reference(s) must teach all of the limitations of the claims.** MPEP § 2143.03. "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984); MPEP § 2141.02. .

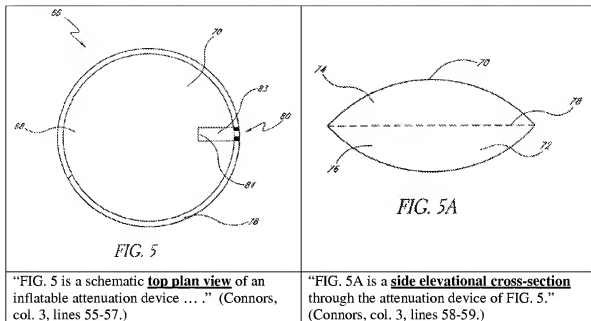
The instant application includes two independent claims, namely, claims 74 and 95. Each such claim is directed to a gastric occlusive device comprising, *inter alia*, a **multilayer film balloon that in an inflated state is non-pillowed and spheroidal in shape.**

In the December 19, 2007 Office Action, the examiner characterized Connors as disclosing "an attenuation device compris[ing] an inflatable container 68 having a **circular profile (see Fig. 5).**" (Office Action, page 2.) Thereafter, the examiner stated:

"[i]n response to Applicants' argument that Connors does not teach a non-pillowed and spheroidal balloon, **it is noted that the balloon of Connors is spheroidal in shape.** Moreover, it would have been obvious to one of ordinary skill in the art that the shape of an article would have been a design choice depending on the user's preference and intended use." (Office Action, page 4.)

NOWHERE has the examiner alleged that Connors enables or suggests any **multi-layer balloon that in an inflated state is also non-pillowed and spheroidal in shape.** To the contrary, Connors *teaches away* from the subject matter of the instant claims – for example, Figures 5-5A of Connors (as reproduced below) illustrate a balloon formed from peripherally bonded polymeric sheets, with the balloon being circular in profile when viewed from above, but clearly **pillowed in character** when viewed from the side. Such pillowed shape along the peripheral seam is the **natural and inevitable result** of forming a balloon by peripherally bonding two conventional non-elastic and non-thermoformed sheets. (See Declaration of Tilak Shah

Under 37 CFR 1.132 as filed on April 23, 2007 (hereinafter "Shah Decl."), ¶ 10-11 and Exhibits A1-A3 thereof.)



Although Connors makes *passing mention* to a spherically-shaped balloon (e.g., Connors, col. 11, lines 18-23), and Connors does disclose certain *non-sheet-based* methods (e.g., dip-molding, Col. 22, lines 41-43, or spray molding, col. 23, lines 62-67) suitable for forming spherical balloons, one skilled in the art would understand that not every balloon fabrication method mentioned by Connors is compatible with every particular balloon shape that is mentioned by Connors. (Shah Decl., ¶ 7.) Indeed, the specific disclosure by Connors (in connection with Connors' Figs. 5-5A) of a flat pillow-like balloon formed from peripherally circular sheets of material **not only represents a lack of enablement of, but also a teaching away from**, fabrication of a non-pillowed and spheroidal balloon formed from peripherally bonded polymer sheets. Thus, the examiner's continued reliance upon Figures 5-5A of Connors (e.g., December 19, 2007 Office Action, pages 2-3) as suggesting the subject matter of Applicant's claims is **clear error**, as such Figures directly **teach away** from any balloon that is non-pillowed and spheroidal in shape when inflated.

Balloons embodying in combination the three features of [1] multi-layer construction, [2] non-pillowed character when inflated, and [3] spheroidal shape when inflated) were **NOT known in the art** at the time the present invention was made. Vacuum thermoforming represents the **only** way (now) known in the art for forming, from two peripherally bonded sections of non-elastic

polymeric film, a balloon that in an inflated state is non-pillowed and spheroidal in shape. (Shah Decl., ¶ 9.) **The use of vacuum thermoforming to fabricate balloons from polymeric sheets was pioneered by the same inventor** as the present application, as evidenced by the issuance of U.S. Patent No. 6,712,832, which broadly claims methods for manufacturing low-pressure balloons from thin film polymeric materials, including the steps of heating the thermoplastic polymeric material thin film to a sufficient temperature for vacuum thermoforming thereof, forming first and second half-sections for a balloon from the thin film by vacuum suction, and bonding the first and second half-sections together along edges thereof. (Shah Decl., ¶ 13-14.) Notably, the subject matter of U.S. Patent No. 6,712,832 was not published (i.e., as U.S. Patent Application Publication No. 2003/0074017) until April 17, 2003 – which date is more than two weeks **after** the filing date of the instant U.S. Patent Application No. 10/815,282, and a month **after** the filing date of U.S. Patent Application No. 10/391,446 that matured into U.S. Patent No. 6,976,950 (Connors).¹

Because vacuum thermoforming represents the only way now known in the art for forming, from two peripherally bonded sections of non-elastic polymeric film, a balloon that in an inflated state is non-pillowed and spheroidal in shape (Shah Decl., ¶ 9), the determination by the USPTO that the balloon fabrication methods involving vacuum thermoforming claimed in U.S. Patent No. 6,712,832 are novel and non-obvious over the prior art – coupled with the lack of public disclosure of the subject matter of U.S. Patent No. 6,712,832 prior to the filing date of Connors – is consistent with the notion that **Connors** (which fails to mention vacuum thermoforming) **cannot be fairly read or interpreted to disclose vacuum thermoforming or any other method for fabricating the subject matter of the amended claims** of the instant application.

Gastric balloons according to Applicant's claims represent an important advance in the art and are clearly distinct in character over prior art balloons. As indicated previously, in a balloon formed by peripherally bonding two conventional non-thermoformed and non-elastic sheets, pillowing along the peripheral seam is a natural and inevitable result. (Shah Decl., ¶ 10; see also Exhibits A1-A3 thereof.) Such pillowing is undesirable in balloons intended for gastric use. (Id.) Pillowing creates involutions resulting in a profile, that in gastric use, tends to abrade the lining of the stomach. (Id.) Moreover, pillowing tends to cause the seam of a gastric balloon to protrude

¹ Due to these facts and the operation of 35 U.S.C. 103(c), neither U.S. Patent No. 6,712,832 nor the corresponding U.S. Patent Application Publication No. 2003/0074017 may be used in any obviousness rejection of the claims of the instant application.

outward, which in extreme cases can cause the seam to act as a cutting edge. (Id.) In contrast, a balloon corresponding to the subject matter of the amended claims of the instant application is non-pillowed, such that upon inflation thereof, the resulting seam between vacuum thermoformed half-sections is devoid of involutions and has a smooth and uniform shape. (Shah Decl., ¶ 10 and Exhibits B1-B3 thereof).

Clear errors in the examiner's rejections of the instant claims may be summed up as follows:

- the examiner has failed to allege (let alone demonstrate) that any multi-layer balloon being spheroidal and non-pillowed upon inflation was **known or achievable in the art** prior to the effective date of the instant application; and
- the examiner reliance upon Figures 5-5A of Connors (which show an obviously pillowed balloon) to support rejections of Applicant's claims is legally untenable, as such figures embodying a **teaching away** from a balloon that is spheroidal and non-pillowed when inflated.

It appears that the examiner is relying upon the bare assertion that "the shape of an article would have been a design choice depending upon user's preference and intended use" to support a hypothetical modification of Connors to yield the subject matter of Applicant's claims. Such bare assertion, however, **IGNORES** the critical fact that **no enabling disclosure corresponding to the subject matter of Applicant's claims was available to the public prior to the filing of the instant application.** Applicant pioneered an entirely new method for forming multi-layer balloons, with such method being uniquely suited to achieve the product now being claimed. The subject matter of Applicant's claims was not achievable according to the teachings of Connors or contemporaries in the art. Accordingly, no support exists for the examiner's purported modification of Connors to yield Applicant's claims.

Based on the foregoing, withdrawal of the claim rejections under 35 U.S.C. 103(a) is warranted, and is respectfully requested. Avoidance of the cost and delay associated with an appeal to the Board to vindicate Applicant's position is desired.